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Pfizer Receives European Approval for Oncology Biosimilar, RUXIENCE™ (rituximab)

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NEW YORK--(BUSINESS WIRE)-- Pfizer Inc. (NYSE: PFE) today announced that the European Commission (EC) has approved RUXIENCE™ (rituximab), a monoclonal antibody (mAb) and biosimilar to MabThera® (rituximab), for the treatment of non-Hodgkin's lymphoma (NHL), chronic lymphocytic leukemia (CLL), rheumatoid arthritis (RA), granulomatosis with polyangiitis (GPA) and microscopic polyangiitis (MPA), and pemphigus vulgaris (PV).[1,2,3]

"The approval of biosimilars such as RUXIENCE is an important development for the treatment of certain cancers and autoimmune conditions," said Igor Aurer, M.D., Ph.D., Professor of Medicine and Head of Hematology Division, University Hospital Centre Zagreb, Croatia. "It's a step toward allowing clinicians an additional treatment option which can help improve access for patients in need of this established medicine."

The EC approval is based on a comprehensive data package which demonstrated biosimilarity of RUXIENCE to the reference product. This includes results from the REFLECTIONS B3281006 clinical comparative study, which evaluated the efficacy, safety and immunogenicity, pharmacokinetics and pharmacodynamics of RUXIENCE and found no clinically meaningful differences in safety or efficacy compared to the reference product in patients with CD20-positive, low tumor burden follicular lymphoma.[4]

"Biosimilars like RUXIENCE exhibit a similar safety and efficacy profile to the originator product and have the potential to improve treatment access while reducing healthcare costs," said Masum Hossain, regional president, Oncology International Developed Markets at Pfizer. "Building on our ongoing commitment to bring biosimilars to market, we look forward to making RUXIENCE available to patients in the EU in the coming months."

Biosimilars have been a significant catalyst for change for the healthcare industry over the last decade, with the potential to help create more sustainable healthcare systems. With more than 10 years of global in-market experience and a portfolio which now includes seven approved biosimilar products in Europe, Pfizer is proud to be a leader and at the forefront of this vital healthcare segment. This approval follows the positive recommendation from the Committee for Medicinal Products for Human Use (CHMP) in January 2020.[5] RUXIENCE was recently made available to adult patients in the United States for the treatment of NHL, CLL, GPA and MPA and also launched in Japan in January 2020.

About RUXIENCE (rituximab biosimilar)

RUXIENCE is a monoclonal antibody (mAb) biosimilar to MabThera which works by targeting a protein called CD20, which is present on the surface of B lymphocytes, also known as B cells. When it attaches to CD20, rituximab helps destroy these B cells.

RUXIENCE safety information

Do not use RUXIENCE if you are allergic to rituximab or other proteins which are like rituximab or any of the other ingredients of this medicine, if you have a severe active infection at the moment or if you have a weak immune system.

RUXIENCE should also not be used if you have severe heart failure or severe uncontrolled heart disease and have rheumatoid arthritis, granulomatosis with polyangiitis, microscopic polyangiitis or pemphigus vulgaris.

Before starting treatment with RUXIENCE, talk to your doctor, pharmacist or nurse if:

- you have ever had or might now have a hepatitis infection. This is because in a few cases, RUXIENCE could cause hepatitis B to become active again, which can be fatal in very rare cases. Patients who have ever had hepatitis B infection will be carefully checked by their doctor for signs of this infection
- you have ever had heart problems (such as angina, palpitations or heart failure) or breathing problems
- you are pregnant, think that you might be pregnant or are planning to become pregnant

Tell your doctor, pharmacist or nurse if you are taking, have recently taken or might take any other medicines. This includes medicines obtained without a prescription and herbal medicines. In particular, tell your doctor if:

- you are taking medicines for high blood pressure
- you have ever taken medicines which affect your immune system – such as chemotherapy or immune-suppressive medicines

If you have been diagnosed with rheumatoid arthritis, granulomatosis with polyangiitis, microscopic polyangiitis or pemphigus vulgaris, also tell your doctor if:

- you think you may have an infection, even a mild one like a cold. The cells that are affected by RUXIENCE help to fight infection and you should wait until the infection has passed before you are given RUXIENCE
- you had a lot of infections in the past or suffer from severeinfections
- you think you may need any vaccinations in the near future, including vaccinations needed to travel to other countries. Some vaccines should not be given at the same time as RUXIENCE or in the months after you receive RUXIENCE

If you are not sure, talk to your healthcare professional before you are given RUXIENCE.

Like all medicines, RUXIENCE can cause side effects, although not everybody gets them. Most side effects are mild to moderate, but some may be serious and require treatment. Rarely, some of these reactions have been fatal.

Infusion reactions

RUXIENCE is given by intravenous infusion into your vein. During or within the first 24-hours of the infusion you may develop fever, chills and shivering. Less frequently, some patients may experience pain at the infusion site, blisters, itching, sickness (nausea), tiredness, headache, breathing difficulties, blood pressure raised, wheezing, throat discomfort, tongue or throat swelling, itchy or runny nose, vomiting, flushing or palpitations, heart attack or low number of platelets. If you have heart disease or angina, these reactions might get worse.

Tell the person giving you the infusion immediately if you develop any of these symptoms, as the infusion may need to be slowed down or stopped. You may require additional treatment such as an antihistamine or paracetamol.

Infections

You might get infections more easily during your treatment with RUXIENCE. Tell your doctor immediately if you get signs of an infection including:

- fever, cough, sore throat, burning pain when passing urine or feeling weak or generally unwell
- memory loss, trouble thinking, difficulty walking or sight loss – these may be due to a very rare, serious brain infection, which has been fatal (Progressive Multifocal Leukoencephalopathy or PML)

If you are being treated for rheumatoid arthritis, granulomatosis with polyangiitis, microscopic polyangiitis or pemphigus vulgaris, you will also find this information in the Patient Alert Card you have been given by your doctor. It is important that you keep this Alert Card and show it to your partner or caregiver. Your doctor will also give you a patient booklet with more detailed information on the risks and symptoms of infections and PML.

Skin reactions

Very rarely, severe blistering skin conditions that can be life-threatening may occur. Redness, often associated with blisters, may appear on the skin or on mucous membranes, such as inside the mouth, the genital areas or the eyelids, and fever may be present. Tell your doctor immediately if you experience any of these symptoms.

Other very common side effects of RUXIENCE treatment include:

If you are being treated for non-Hodgkin’s lymphoma or chronic lymphocytic leukemia:

- bacterial or viral infections, bronchitis
- low number of white blood cells, with or without fever or blood cells called “platelets”
- feeling sick (nausea)
- bald spots on the scalp, chills, headache
- lower immunity – because of lower levels of antibodies called “immunoglobulins” (IgG) in the blood which help protect against infection

If you are being treated for rheumatoid arthritis:

- infections such as pneumonia (bacterial)
- pain on passing water (urinary tract infection)
- allergic reactions that are most likely to occur during an infusion, but can occur up-to 24-hours after infusion
- changes in blood pressure, nausea, rash, fever, feeling itchy, runny or blocked nose and sneezing, shaking, rapid heartbeat, and tiredness
- headache
- changes in laboratory tests carried out by your doctor. These include a decrease in the amount of some specific proteins in the blood (immunoglobulins) which help protect against infection

If you are being treated for granulomatosis with polyangiitis or microscopic polyangiitis:

- infections, such as chest infections, pain on passing water (urinary tract infections), colds and herpes infections
- allergic reactions that are most likely to occur during an infusion, but can occur up-to 24-hours after infusion

- diarrhea
- coughing or shortness of breath
- nose bleeds
- raised blood pressure
- painful joints or back
- muscle twitches or shakiness
- feeling dizzy
- tremors (shakiness, often in the hands)
- difficulty sleeping (insomnia)
- swelling of the hands or ankles

If you are being treated for pemphigus vulgaris:

- allergic reactions that are most likely to occur during an infusion, but can occur up to 24 hours after infusion
- long lasting depression
- loss of hair

RUXIENCE may also cause changes in laboratory tests carried out by your doctor. If you are having RUXIENCE with other medicines, some of the side effects you may get may be due to the other medicines.

Please refer to the European Summary of Product Characteristics for RUXIENCE for complete safety information**.**

About Pfizer Oncology

At Pfizer Oncology, we are committed to advancing medicines wherever we believe we can make a meaningful difference in the lives of patients. Today, Pfizer Oncology has an industry-leading portfolio of 22 approved innovative cancer medicines and biosimilars across more than 30 indications, including breast, prostate, kidney and lung cancers, as well as leukemia and melanoma. Pfizer Oncology is striving to change the trajectory of cancer.

Pfizer Inc.: Breakthroughs that change patients' lives®

At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety and value in the discovery, development and manufacture of health care products, including innovative medicines and vaccines. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as one of the world's premier innovative biopharmaceutical companies, we collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable healthcare around the world. For more than 150 years, we have worked to make a difference for all who rely on us. We routinely post information that may be important to investors on our website at www.pfizer.com. In addition, to learn more, please visit us on www.pfizer.com and follow us on Twitter at @Pfizer and @Pfizer_News, LinkedIn, YouTube and like us on Facebook at Facebook.com/Pfizer.

DISCLOSURE NOTICE: The information contained in this release is as of April 2, 2020. Pfizer assumes no obligation to update forward-looking statements contained in this release as the result of new information or future events or developments.

This release contains forward-looking information about RUXIENCE, including its potential benefits, that involves substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Risks and uncertainties include, among other things, uncertainties regarding the launch timing and commercial success of RUXIENCE in the EU; the uncertainties inherent in research and development, including the ability to meet anticipated clinical endpoints, commencement and/or completion dates for our clinical trials, regulatory submission dates, regulatory approval dates and/or launch dates, as well as the possibility of unfavorable new clinical data and further analyses of existing clinical data; the risk that clinical trial data are subject to differing interpretations and assessments by regulatory authorities; whether regulatory authorities will be satisfied with the design of and results from our clinical studies; whether and when applications for RUXIENCE may be filed in any other jurisdictions; whether and when regulatory authorities in any other jurisdictions may approve any such other applications for RUXIENCE that may be pending or filed, which will depend on myriad factors, including making a determination as to whether the product's benefits outweigh its known risks and determination of the product's efficacy and, if approved, whether RUXIENCE will be commercially successful; intellectual property and/or litigation implications; decisions by regulatory authorities impacting labeling, manufacturing processes, safety and/or other matters that could affect the availability or commercial potential of RUXIENCE; uncertainties regarding access challenges for our biosimilar products where our product may not receive appropriate formulary access or remains in a disadvantaged position relative to the innovator product; and competitive developments.

A further description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2019 and in its subsequent reports on Form 10-Q, including in the sections thereof captioned "Risk Factors" and "Forward-Looking Information and Factors That May Affect Future Results", as well as in its subsequent reports on Form 8-K, all of which are filed with the U.S. Securities and Exchange Commission and available at www.sec.gov and www.pfizer.com

[1] Pfizer. Data on File. European Commission Approval Letter 2020.

[2] MabThera is a registered trademark of Roche, Inc.

[3] European Medicines Agency. MabThera EPAR Summary for the Public. Available at http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Summary_for_the_public/human/000165/WC500025815.pdf. Accessed April 2020.

[4] Sharman J, et al. A Randomized, Double-Blind Efficacy and Safety Study of PF-05280586 (a Potential Rituximab Biosimilar) Compared with Rituximab Reference Product (MabThera) in Subjects with Previously Untreated CD20-Positive, Low Tumor Burden Follicular Lymphoma (LTB-FL). BioDrugs. 2019. Doi:10.1007/s40259-019-00398-7

[5] European Medicines Agency. RUXIENCE Summary of Opinion. Available at https://www.ema.europa.eu/en/medicines/human/summaries-opinion/ruxience. Accessed April 2020.

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